Should we use mechanical valves in patients with end-stage renal disease?

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Abstract

A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was whether a mechanical or bioprosthetic valve is superior for immediate and long-term survival in patients with end-stage renal disease (ESRD) undergoing a valve replacement. Altogether more than 150 papers were found using the reported search; of which, eight represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. There were no randomized controlled trials addressing the question. There was one systematic review and meta-analysis. All the other evidence was in the form of retrospective studies. The papers show that there is no significant difference in the results and survival between patients receiving a mechanical and those receiving a bioprosthetic valve. This was seen in the meta-analysis as well as the larger series of patients who underwent valve replacement. Bleeding complications were more common with mechanical valves. We conclude that the choice of valve for patients with ESRD should be determined by age, level of activity and patient choice. Due to the limited life expectancy of these patients, bioprosthetic valves should be considered, especially since there is no evidence of early degeneration of tissue valves in this subgroup of patients.

Keywords: Valve replacement • Dialysis • Mechanical • Tissue

INTRODUCTION

A best evidence topic was constructed according to a structured protocol. This is fully described in the ICVTS [1].

THREE-PART QUESTION

In [patients with end-stage renal disease undergoing a valve replacement] is [a mechanical or a bioprosthetic valve] superior [for immediate and long-term survival].

CLINICAL SCENARIO

In a multidisciplinary team meeting, a 55-year old patient with end-stage renal disease (ESRD) is referred for a valve replacement. You would usually place a mechanical valve in patients of this age but you wonder, with his regular dialysis, potential for renal transplantation and reduced life expectancy, whether a tissue valve would not be better for him so that he can avoid warfarin. You decide to review the literature on this subject.

SEARCH STRATEGY

Medline 1948 to November 2011 with OVID SP (exp Heart Valve Prosthesis/ OR valve replacement.mp. OR AVR.mp) AND (end stage renal disease.mp. or exp Kidney Failure, Chronic/ OR exp Renal Dialysis/ or haemodialysis.mp).

SEARCH OUTCOME

Two hundred and forty-seven papers were found using the reported search. From these, eight papers were identified, which provided the best evidence to answer the question. These are presented in Table 1.

RESULTS

Thourani et al. [2] studied 211 operations on dialysis patients. One hundred and forty-three received the bioprosthetic (67.8%) and 68 (32.2%) mechanical valves. There was no statistically significant difference in major adverse cardiac adverse factors or survival between the bioprosthetic and mechanical valves.

Herzog et al. [3] studied 5858 dialysis patients needing a valve replacement. The criterion for the inclusion of this study was patients who had undergone dialysis for at least 30 days prior to
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<td>Thourani et al. (2011), Ann Thorac Surg [2], USA</td>
<td>202 patients needing 211 replacements. 143 patients received bioprosthetic valves (143 of 211, 67.8%), while 68 of 211 (32.2%) received mechanical valves</td>
<td>30-day mortality and 10-year survival</td>
<td>143 patients received bioprosthetic valves (143 of 211, 67.8%), while 68 of 211 (32.2%) received mechanical valves. Concomitant coronary artery bypass was performed in 53 of 211 (25.1%) patients. 30-day mortality was in 42 of 211 patients (19.9%) and was not different between bioprosthetic and mechanical valve replacements. Overall 10-year survival was 18.1% for all patients and was not influenced by the valve type implanted</td>
<td>Long-term survival is similar among patients receiving bioprosthetic or mechanical valve replacement</td>
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<td>Herzog et al. (2002), Circulation [3] USA</td>
<td>5858 dialysis patients undergoing valve surgery with tissue valves were used in 881 patients</td>
<td>30-day mortality and 2-year survival</td>
<td>The in-hospital mortality of 5858 dialysis patients undergoing valve surgery was 20.7%. Tissue valves were used in 881 patients. There was no significant difference in survival related to the type of prosthetic valve implanted. The 2-year survival rate was 39.7 ± 3.5% with tissue valves and 39.7 ± 1.4% for non-tissue valves. Compared with non-tissue prosthetic valves, the use of tissue valves was not predictive of death (RR 0.98; 95% CI 0.90–1.07)</td>
<td>There is no significant difference in the survival of dialysis patients after cardiac valve replacement with tissue versus non-tissue prosthetic valves</td>
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<td>Brinkman et al. (2002), Ann Thorac Surg [4] USA</td>
<td>72 patients needing 95 valve procedures 58 mechanical valves (66%) 30 bioprosthetic (34%)</td>
<td>Significant bleeding/stroke and overall survival</td>
<td>50% of patients who had mechanical valve replacement had a significant bleeding/stroke. In comparison, only 8.3% had the same outcome in the bioprosthetic group (P = 0.016, Fisher’s exact test for differences; odds ratio 6.02). Operative survival was 84% for those patients with mechanical replacement and 86% for those with bioprosthetic replacement. There was no difference between the late survival in the two groups (Kaplan–Meier)</td>
<td>There is a 6-fold increase in bleeding complication in the mechanical valve replacement group and therefore, bioprosthetic valves should be the valve substitute of choice</td>
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<td>Chan et al. (2006), Ann Thorac Surg [5] USA</td>
<td>69 patients needing 22 mechanical and 47 bioprosthetic valve</td>
<td>5-year survival and 5-year freedom from complication</td>
<td>Freedom from all valve-related complications was 82.8 ± 8.1% in the bioprosthetic valve replacement group and 76.4 ± 12.7% in the mechanical valve replacement group (P &gt; 0.05). 5-year survival in the mechanical valve replacement group was 52 ± 12.9% while in the bioprosthetic valve replacement group, it was 21.9 ± 7.1% (P = 0.0299)</td>
<td>There is no difference in freedom from complication and structural valve deterioration between both groups. Therefore, bioprostheses should be considered</td>
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<tr>
<td>Filsoufi et al. (2008) [6] Nephrol Dial Transplant, UK</td>
<td>155 patients with renal failure, 50 mechanical and 63 bioprosthetic</td>
<td>Mortality and 5-year survival rate</td>
<td>Hospital mortality similar between the two groups (Group 1: 23%, Group 2: 18%). Mortality of patients during the follow-up period for patients who were on dialysis (39%) compared to not being on dialysis (37%) was not significantly higher. 5-year survival rate for biological valve replacement was 51 ± 10.7 while mechanical valve replacement was 55 ± 8.4</td>
<td>Both mortality and morbidity are high in patients with RF whether they are dialysis-dependent or not and the type of prosthesis did not impact survival</td>
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valvular surgery. However patients who received concomitant CABG were at increased risk of death by 8%. Tissue valves were used in 881 patients. There was no significant difference in survival related to the type of prosthetic valve implanted. The use of tissue valves was not predictive of death relative risk (RR 0.98; 95% confidence interval (CI) 0.90–1.07). They concluded that there is no significant difference in the survival of dialysis patients after a tissue or mechanical valve replacement. However, the study found that older age (≥75 years), diabetic end-stage renal failure (ESRD), liver disease and double valve replacement to be predictors of death.

Brinkman et al. [4] studied 72 patients. Out of 34 patients with mechanical valves, 17 had significant bleeding or stroke (50%). Only 1 in 12 patients (8.3%) who had bioprosthetic valve replacement had the same outcome (P = 0.016, odds ratio 6.02). Overall early and late survival between the two groups did not differ significantly. They concluded that bioprosthetic valves should be chosen due to the 6-fold increase in bleeding complications in the mechanical valve replacement group.

Chan et al. [5] studied 69 valve replacements; 47 bioprosthetic and 22 mechanical. Freedom from all valve-related complications was 82.8 ± 8.1% in the bioprosthetic valve group and 76.4 ± 12.7% in the mechanical group (not significant). Five-year survival in the mechanical valve replacement group was 52 ± 29.9%, while it was 21.9 ± 7.1% in the bioprosthetic group. This was significant (P = 0.0299). However, patients with bioprosthetic valves were older, had more past MIs myocardial infarctions and had more concomitant revascularization procedures. They concluded that there was no difference in freedom from complications between mechanical and bioprosthetic valve replacement groups.

Filsoufi et al. [6] studied 155 patients with a valve replacement. They concluded that both mortality and morbidity are high in patients with RF regardless of whether they are dialysis-dependent or not, and that the type of prosthesis did not affect the survival.

Tanaka et al. [7] studied 73 dialysis patients with aortic valve replacements (51 mechanical and 22 bioprosthetic). In these patients, the valve-related complication was similar. Six of 51 patients in the mechanical group and one of 22 patients in the bioprosthetic group had bleeding risk. Similarly, there were five thromboembolic events in the mechanical group and one in the bioprosthetic group. The valve-related survival rate in both groups was not significantly different (P = 0.202), but the all-cause survival rate in the bioprosthetic group was significantly worse (P < 0.001). The authors concluded that valve selection and surgical strategy must be considered on a case-to-case basis to improve the clinical outcomes.

Boeken et al. [8] analysed retrospective data from 104 patients with ESRD who underwent valve replacements. Forty-two patients had more concomitant revascularization procedures. They concluded that there was no difference in freedom from complications between mechanical and bioprosthetic valve replacement groups.

Table 1: Continued

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<tr>
<td>Tanaka et al. (2010), Ann Thorac Surg [7] USA</td>
<td>73 patients had 51 mechanical valve replacements and 22 bioprosthetic valve replacement</td>
<td>Valve-related complication and survival rate</td>
<td>Valve-related complication was documented in 12 of 44 patients in the mechanical valve replacement group and 2 of 21 in the bioprosthetic valve replacement group (P = 0.38). The valve-related survival rate in both groups were not significantly different (P = 0.202) but the all-cause survival rate in the bioprosthetic valve replacement group was significantly worse (P &lt; 0.001)</td>
<td>Valve selection and surgical strategy must be considered on a case-to-case basis to improve the clinical outcomes</td>
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<td>Boeken et al. (2010), Thorac Cardiovasc Surg [8] UK</td>
<td>104 patients had valve replacement over 6 years. 54 had a bioprosthesis and 50 mechanical valve replacement</td>
<td>Valve-related complication and mortality</td>
<td>Inpatient mortality was not significantly different at 13.6% for mechanical valves and 11.7% for bioprosthetic valves. Cerebrovascular events occurred in 18% of those following mechanical replacement and 8.3% for bioprosthetic; this was significant P &lt; 0.05</td>
<td>No significant difference in mortality, however, biological valves have a reduced risk of complications</td>
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<td>Chan et al. (2011), Heart [9] UK</td>
<td>Nine studies reviewed, 3741 aortic, 598 aortic and mitral valve replacements</td>
<td>Valve-related complications and survival rates &gt;12 years</td>
<td>No difference in the survival rate between valve types (P &lt; 0.05). Valve-related complications included bleeding and re-operation. Bleeding occurred 0.75% in mechanical versus 0.1% in bioprosthesis. The overall difference in complications was not significant (P = 0.2)</td>
<td>Survival is not related to the type of valve implanted. A slight increase in the risk of complications with the mechanical prosthesis use</td>
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replacements had a significantly higher rate of postoperative cerebrovascular accidents (18.2%) compared with those with biological replacement (8.3%, P < 0.05). The other bleeding complications were also significantly higher (15.9 versus 11.7%, P < 0.05). The authors concluded that biological valves should be the preference as the use of mechanical valves is associated with a significant risk of complications.

Chan et al. performed a systematic review and meta-analysis of valve replacement in patients with ESRD on dialysis. Twelve studies, published from 1997 to 2010, were included in this review; of which, nine were used in the meta-analysis. No difference in the survival was observed between the valve types (bioprostheses versus mechanical prostheses; hazard ratio 1.3, 95% CI 1.0–1.9, P = 0.09). However, bioprosthetic valves were associated with a fewer valve-related complications compared with mechanical prostheses (odds ratio 0.4, 95% CI 0.2–0.7, P = 0.002). They concluded that there was no survival difference following valve replacement with either bioprostheses or mechanical prostheses in patients with ESRD on dialysis. Bioprosthetic valve replacement was associated with fewer valve-related complications.

CLINICAL BOTTOM LINE

We conclude that the choice of valve in the patients with ESRD should be determined by age, level of activity and patient choice. There is no sufficient evidence to recommend mechanical or tissue valves. Due to the limited life expectancy of these patients, bioprosthetic valves should be considered especially since there is no evidence of early degeneration of tissue valves in this subgroup of patients.

Conflict of interest: none declared.

REFERENCES


eComment. Are mechanical valves better than bioprostheses in patients on dialysis?

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We read with great interest the article by Pai et al. regarding the best valve substitute in patients on dialysis [1]. They included in the results of their research, seven retrospective studies and one meta-analysis. However, we found 4 other relevant articles investigating the same problem. In order to be exhaustive, we will summarize the relevant results of these studies and highlight the safety of implanting bioprosthesis in patients on chronic dialysis.

The standard of valve selection has changed over time. It has long been believed that tissue valves undergo premature degeneration due to the derangements in calcium metabolism in patients with end-stage renal disease. This is based on largely anecdotal case reports using first generation bioprostheses. In 1998, ACC/AHA guidelines recommended the use of mechanical valves in patients on dialysis. Accumulating data supporting the very low incidence of rapid tissue valve degeneration in dialysis patients had been taken into consideration, and the latest ACC/AHA practice guidelines do not specify the best choice for valve replacement in dialysis patients. Only four cases of structural valve deterioration (SVD) requiring reoperation were identified from the meta-analysis [1], ranging from 10 to 96 months after the initial valve replacement surgery. However, conclusions on the long-term performance of tissue valves in this patient population cannot be drawn. Bleeding was the most common valve-related complication, and represented a major drawback of mechanical valves.

Lucke et al. [2] reviewed 19 consecutive patients with end-stage renal disease from a single institution who had undergone aortic, mitral or aorto-mitral valve replacement, 9 had a bioprosthetic valve and 10 a mechanical valve. Mechanical valve patients had a significantly higher rate of postoperative cerebrovascular events or bleeding complications. No subsequent reoperations were required for biological valve failure. The overall estimated Kaplan-Meier survival was 42% ± 14% at 60 months. Kaplon et al. [3] from The Cleveland Clinic Foundation, found comparable results for both types of valves when reviewing 42 patients on preemptive dialysis undergoing valve replacements. Seventeen patients received mechanical valves and 25 received bioprostheses. Four patients with a bioprosthesis required reoperation, one of whom experienced mitral bioprosthesis degeneration. Prosthetic valve-related complications and survival were similar for both mechanical and bioprosthetic valves. Toole et al. [4] reviewed 50 dialysis patients undergoing left-sided valve replacement. The tissue valve group had a higher Kaplan-Meier freedom from valve-related morbidity and mortality at three years. Freedom from reoperation was not significantly different. Umezu et al. [5] analyzed data from 63 consecutive dialysis patients who underwent valvular surgery. The mechanical group had a higher rate of bleeding events. There was no case of SVD up to the 5-year follow-up. However, both mechanical and bioprosthetic valve patients had similar survival and event-free rates. It can be concluded that dialysis patients after cardiac valve replacement suffer poor mid- and long-term survival. Therefore, surgeons should not hesitate to implant bioprosthetic valves because SVD will be uncommon in this patient population.

Conflict of interest: None declared.

References